Complete Summary

GUIDELINE TITLE

Diagnosis and treatment of osteoporosis.

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Diagnosis and treatment of osteoporosis. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2005 Sep. 61 p. [162 references]

GUIDELINE STATUS

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Osteoporosis

GUIDELINE CATEGORY

Diagnosis
Evaluation
Prevention
Risk Assessment
Treatment

CLINICAL SPECIALTY

Endocrinology
Family Practice
Geriatrics
Internal Medicine
Preventive Medicine
Rheumatology

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Health Plans
Hospitals
Managed Care Organizations
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To improve diagnostic and therapeutic follow-up of adults presenting with a history of low impact fracture
- To increase the evaluation for osteoporosis risk factors in all adults presenting for a preventive visit, and stratify into appropriate risk group

TARGET POPULATION

- Men and women at risk for osteoporosis
- Men and women with suspected or confirmed osteoporosis

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Risk Assessment/Prognosis/Evaluation

1. Assessment for and discussion of risk factors for osteoporosis
2. Serial height measurements with a stadiometer
3. Assessment of posture
4. Lateral vertebral assessment with dual x-ray absorptiometry (DEXA) or radiographs of the thoracic and lumbar spine as indicated
5. Measurement of bone mineral density (BMD) as indicated
6. Laboratory evaluation of patients with osteoporosis to assess for secondary causes of osteoporosis (tests vary depending on patient features)

Prevention and/or Treatment of Osteoporosis

1. Lifestyle counseling regarding measures to prevent fractures (exercise, smoking cessation, alcohol restriction, dietary counseling, weight, environmental modification to prevent falls, measures to reduce the impact of falls [such as soft hip protector pads])
2. Vitamin D and calcium supplementation

3. Pharmacologic agents
    - Bisphosphonates (alendronate [Fosamax®], risedronate [Actonel®], and ibandronate [Boniva®]) (treatment and prevention)
    - Selective estrogen receptor modulator (SERM) (Raloxifene [Evista®]) (treatment and prevention)
    - Calcitonin (Calcitonin-salmon [Miacalcin® injection and nasal spray, (treatment)
    - Estrogens (prevention)
    - Parathyroid hormone 1-34 (teriparatide) (Forteo®)
4. Physical therapy
5. Follow-up bone mineral density testing (with dual x-ray absorptiometry [DXA] at a central site after pharmacologic intervention to assess changes in bone mineral density.

Note:

- Routine supplementation with the following alternative and complementary agents has either not been studied or not shown benefit for treatment of osteoporosis: phytoestrogens, synthetic isoflavones such as ipriflavone, natural progesterone cream, magnesium, vitamin K, eicosapentaenoic acid and gamma-linolenic acid, and Kampo formulae
- Guideline developers listed and commented on, but did not recommend, the following non-FDA-approved treatments for osteoporosis: (bisphosphonates: etidronate [Didronel®], pamidronate [Aredia®], and zoledronic acid [Zometa®]; calcitriol [Rocaltrol®]; ergocalciferol [Calciferol®]; nandrolone decanoate; sodium fluoride; tamoxifen [Nolvadex®]; testosterone; tibolone, and strontium ranelate)

MAJOR OUTCOMES CONSIDERED

- Fracture risk (absolute risk, relative risk, and incidence)
- Predictive value of bone mineral density measurements
- Effects of prevention/treatment interventions on bone density, bone loss, bone health, and fracture risk

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

No additional description of literature search strategies is available.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion. Individual studies are classed according to the system presented below and are designated as positive, negative, or neutral to reflect the study quality.

Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results of different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

Study Quality Designations:

The quality of the primary research reports and systematic reviews are designated in the following ways on the conclusion grading worksheets:

Positive: indicates that the report or review has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis.

Negative: indicates that these issues (inclusion/exclusion, bias, generalizability, and data collection and analysis) have not been adequately addressed.

Neutral: indicates that the report or review is neither exceptionally strong nor exceptionally weak.

Not Applicable: indicates that the report is not a primary reference or a systematic review and therefore the quality has not been assessed.

Classes of Research Reports:

A. Primary Reports of New Data Collection:

Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Non-randomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M:

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

The guideline developers reviewed published cost analysis.

METHOD OF GUIDELINE VALIDATION

Clinical Validation-Pilot Testing
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Institute Partners: System-Wide Review

The guideline draft, discussion, and measurement specification documents undergo thorough review. Written comments are solicited from clinical, measurement, and management experts from within the member medical groups during an eight-week period of "Critical Review."

Each of the Institute's participating medical groups determines its own process for distributing the guideline and obtaining feedback. Clinicians are asked to suggest modifications based on their understanding of the clinical literature coupled with their clinical expertise. Representatives from all departments involved in implementation and measurement review the guideline to determine its operational impact. Measurement specifications for selected measures are developed by the Institute for Clinical Systems Improvement (ICSI) in collaboration with participating medical groups following general implementation of the guideline. The specifications suggest approaches to operationalizing the measure.

Guideline Work Group: Second Draft

Following the completion of the "Critical Review" period, the guideline work group meets 1 to 2 times to review the input received. The original guideline is revised as necessary, and a written response is prepared to address each of the suggestions received from medical groups. Two members of the Committee on Evidence-Based Practice carefully review the Critical Review input, the work group responses, and the revised draft of the guideline. They report to the entire committee their assessment of two questions: (1) Have the concerns of the medical groups been adequately addressed? (2) Are the medical groups willing

and able to implement the guideline? The committee then either approves the guideline for pilot testing as submitted or negotiates changes with the work group representative present at the meeting.

Pilot Test

Medical groups introduce the guideline at pilot sites, providing training to the clinical staff and incorporating it into the organization's scheduling, computer, and other practice systems. Evaluation and assessment occur throughout the pilot test phase, which usually lasts for three months. Comments and suggestions are solicited in the same manner as used during the "Critical Review" phase.

The guideline work group meets to review the pilot sites' experiences and makes the necessary revisions to the guideline, and the Committee on Evidence-Based Practice reviews the revised guideline and approves it for implementation.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary. The recommendations that follow are based on the previous version of the guideline.

Note from the National Guideline Clearinghouse (NGC) and the Institute for Clinical Systems Improvement (ICSI): In addition to updating their clinical guidance, ICSI has developed a new format for all guidelines. Key additions and changes include: combination of the annotation and discussion section; the addition of "Key Points" at the beginning of most annotations; the inclusion of references supporting the recommendations; and a complete list of references in the Supporting Evidence section of the guideline. For a description of what has changed since the previous version of this guidance, refer to Summary of Changes -- September 2005.

The recommendations for the diagnosis and treatment of osteoporosis are presented in the form of an algorithm with 15 components, accompanied by detailed annotations. An algorithm is provided for Diagnosis and Treatment of Osteoporosis; clinical highlights and selected annotations (numbered to correspond with the algorithm) follow.

Class of evidence (A-D, M, R, X) and conclusion grade (I-III, Not Assignable) definitions are repeated at the end of the "Major Recommendations" field.

Clinical Highlights

1. Discuss risk factors for osteoporosis and primary prevention with all patients presenting for preventive health visits. (Annotations #4, 5)
2. Patients with a high pretest probability of low bone mineral density (BMD) and future fracture should have bone density testing to further define their fracture risk. (Annotation #8)

3. Address pharmacologic options for prevention and treatment of osteoporosis with appropriate patients at risk for or who currently have signs and symptoms of osteoporosis. (Annotation #14)

Diagnosis and Treatment of Osteoporosis Algorithm Annotations

1. All Patients Presenting for a Preventive Visit

   Osteoporosis is the consequence of continued bone loss throughout adulthood. The guideline developers recommend maintaining peak bone mass for all patients. To achieve this, patients should have risks for osteoporosis reviewed when they present to their provider offices. In addition to reviewing historical risk factors (discussed in Annotation #5, "Discuss Risk Factors for Osteoporosis and Osteoporotic Fracture"), it is important to record accurate serial height measurements with a stadiometer and observe posture for kyphosis. Patients with significant acquired kyphosis and/or a height loss of one inch should have lateral vertebral assessment with dual x-ray absorptiometry (DXA) or thoracic and lumbar spine radiographs and bone density testing.

   Evidence supporting this recommendation is of class: R

2. Patient With a Low-Impact Fracture

   Key Points:

   - Low impact fracture defines osteoporosis and requires therapy.

   Discuss osteoporosis risk with any adult who has a history of a low-trauma fracture that may be related to osteoporosis. For the purpose of this guideline, a low-impact fracture will be defined as a fracture occurring spontaneously or from a fall at a height no greater than the patient's standing height, including fragility fractures occurring from activities such as a cough, sneeze, or abrupt movement (e.g., opening a window), and patients who have vertebral compression fracture documentation on radiographs regardless of their degree of symptoms. Many adults do not realize that having one fracture in their adult lifetime indicates an increased risk of future fractures, especially in the first few years following the fracture, and may be an indication for bone density testing. This historical risk factor provides information that may be additive to bone mineral density information. The occurrence of a fracture, particularly in the limbs, is followed by accelerated bone loss, not completely reversible, which could lead to an increased risk of subsequent fracture. And, there may be mechanical influences caused by having had one fracture, that increase subsequent risk by altering balance and increasing fall risk.

   Post-Fracture Recommendations

   - Consider all adults with a history of vertebral fracture, hip fracture, or distal forearm fracture at higher than average risk for a future fracture.

- Review lifestyle risk factors for osteoporosis. Discuss adequacy of total calcium and vitamin D intake. Address home safety and fall prevention.
- Consider bone density testing in fracture patients willing to accept treatment.
- Consider all men* and postmenopausal women with low impact fracture as candidates for osteoporosis treatment.
- Women over age 70 with prior fracture are candidates for osteoporosis therapy even without bone density testing.

  *Although the best data available is on postmenopausal women, there may be a similar risk in men, and the guideline developers are including men in this guideline recommendation.

Refer to the original guideline document for more information.

Evidence supporting this recommendation is of classes: A, B, C, D, M, R

3. Patient On Chronic Glucocorticoid Use or Transplant Recipient

   Key Points:

   - Glucocorticoid use compounds fracture risk beyond that as determined by bone mineral density (BMD)

   Glucocorticoid Use

   Osteoporosis prevention and treatment measures and bone mineral density testing should be considered for anyone who is started on or has been on exogenous systemic glucocorticoid therapy (at a dose of more than 5 mg prednisone or equivalent per day for 3 or more months). Osteoporosis prevention measures should also be considered for those who have been or can be expected to be on a daily high-dose inhaled glucocorticoid for several years. While it is never too late in the course of glucocorticoid therapy to prevent or treat osteoporosis, it is preferable to start preventive measures against bone loss at the time glucocorticoids are commenced for two reasons. First, the greatest amount of bone is lost during the first several months of glucocorticoid use. Second, the risk of fracture at any given level of bone mineral density is greater in those on chronic glucocorticoid therapy than in those who are not on a glucocorticoid. That is, fracture risk is disproportionately increased in those with glucocorticoid-induced low bone density relative to those with low bone density associated with the aging process and/or the postmenopausal state.

   Refer to the original guideline document for information on bone mineral density loss and fracture associated with oral and inhaled glucocorticoids.

   Organ Transplantation

Solid organ transplantation of all types and allogeneic bone marrow transplantation are associated with rapid bone loss after transplantation. In addition, many patients develop significant bone loss before transplantation.

Refer to the original guideline document for more information on pre- and post-transplantation bone loss.

Evidence supporting this recommendation is of classes: B, D

4. Discuss Primary Prevention of Fractures

Key Points:

- Healthy lifestyle discussion at primary prevention visits is important for osteoporosis prevention.

Body Habitus

Low body mass index (BMI) (less than 20) is a strong independent risk factor for osteoporosis and fracture. Weight less than 127 pounds, associated with small bones, is a risk factor for osteoporosis. Primary prevention should include counseling patients on achievement and maintenance of a healthy body weight (BMI between 20 and 25). A balanced diet including dairy products and appropriate nutrition should be discussed with patients. Also see Annotation #5, "Discuss Risk Factors for Osteoporosis and Osteoporotic Fracture."

Evidence supporting this recommendation is of class: B

Gonadal Hormonal Status

Women who are prematurely hypogonadal and hypogonadal men who are at increased risk for fracture should be considered for replacement therapy. For further information, please see Discussion #13, "Consider Secondary Causes and Further Diagnostic Testing" as well as Annotation #14, "Address Options for Prevention or Treatment of Osteoporosis," in the original guideline document.

Exercise

Exercise is well known for its many benefits both short-term and long-term. Weight bearing and muscle strengthening exercises have been shown to be an integral part of osteoporosis prevention as well as a part of the treatment process.

Refer to the original guideline document for more information.

Evidence supporting this recommendation is of classes: D, R

Smoking Cessation

Smoking cessation counseling should be done at every visit. Discussion can include helpful strategies such as nicotine replacement therapy with patches, gum, etc. Bupropion and available smoking cessation classes may also be discussed. For more information on smoking cessation, please refer to the National Guideline Clearinghouse (NGC) summary of the Institute for Clinical Systems Improvement (ICSI) guideline, Tobacco Use Prevention and Cessation for Adults and Mature Adolescents.

Alcohol Restriction

Limit alcohol use to no more than two drinks per day. One drink equals 12 ounces of beer, 5 ounces of wine, or 1.5 ounces of 80-proof distilled spirits. This limit will help to protect bone health and reduce the risk of falls. See Annotation #5, "Discuss Risk Factors for Osteoporosis and Osteoporotic Fractures."

Evidence supporting this recommendation is of classes: A, D, R

Calcium

Adequate calcium intakes from food sources and supplements promote bone health. Calcium also supports estrogen's positive effect on bone health. When food sources do not provide enough calcium, supplements can be used to meet this goal. Bioavailability of calcium in food sources and supplements is a factor in achieving daily calcium recommendations. Calcium supplement labels should indicate lead testing.

Daily elemental calcium recommendations for healthy individuals include:

National Academy of Sciences, Institute of Medicine (1997)

- 9-18 years: 1,300 mg
- 19-50 years: 1,000 mg
- Over 50 years: 1,200 mg
- Maximum limit: 2,500 mg

However, for people with established osteoporosis, glucocorticoid use, pregnant or nursing women, or persons over the age of 65, it may be more appropriate to recommend 1,500 mg.

Calcium slows age-related bone loss. [Conclusion Grade II, See Conclusion Grading Worksheet -- Appendix A of the original guideline document, -- Annotations #4 & 5 (Calcium)]

Calcium may reduce osteoporosis fracture risk. [Conclusion Grade III, See Conclusion Grading Worksheet -- Appendix A of the original guideline document, -- Annotations # 4 & 5 (Calcium)]

Refer to the original guideline document for more information.

Vitamin D

Adequate vitamin D intake supports calcium absorption and bone metabolism. Since sunlight exposure cannot be assumed to produce needed vitamin D, dietary sources are essential. Since many adults in northern climates are deficient in vitamin D, supplements are often needed to meet daily requirements. The following guidelines assume no vitamin D is synthesized from sunlight exposure:

Institute of Medicine (1997)*

- 19-50 years: 200 IU/day
- 51-70 years: 400 IU/day
- over 70 years: 600 IU/day
- Maximum limit: 2,000 IU/day

*These guidelines are currently under revision and the recommendation for adults will likely be significantly increased to 800-1,000 IU/day. Supplementation should be made to maintain 25-OH vitamin D levels greater than 30 ng/mL.

Although milk is the only dairy source of vitamin D, studies have demonstrated highly variable levels of vitamin D fortification in milk in both the U.S. and Canada. Other food sources of vitamin D are affected by the time of year they are harvested.

Prevention of Falls

Preventing falls reduces fractures and fracture risk. Modifying environmental, personal risk, and medication-related factors can be effective in reducing falls. Home visits may help with this. Hip protector pads for frail, elderly adults have been shown to reduce hip fractures in some studies.

Please, see Annotation #5, "Discuss Risk Factors for Osteoporosis and Osteoporotic Fracture."

5. Discuss Risk Factors for Osteoporosis and Osteoporotic Fracture

The following are risk factors for osteoporosis and osteoporotic fracture:

- Female
- Advanced age (greater than age 65)
- Body habitus (weight less than 127 pounds; or body mass index [BMI] $\leq$20)
- Caucasian or Asian race
- Personal or family history of fracture (first-degree relative)
- Hypogonadism (estrogen or testosterone deficiency)
- Sedentary lifestyle
- Smoking
- Excessive alcohol intake (more than two drinks per day)
- Diet deficient in calcium or vitamin D without adequate supplementation
- Increased likelihood of falling

For a list of secondary causes of osteoporosis, please see Annotation Appendix A, "Secondary Causes of Osteoporosis" in the original guideline document.

Risk factors for osteoporosis and fractures are fixed or modifiable. Some risk factors for osteoporosis are also risk factors for fracture independent of bone mineral density. They are important to know so they can be assessed and modified if possible.

Advanced age, female gender, Caucasian and Asian race, and hypogonadal states are risk factors for osteoporosis. The only one of these that is modifiable is hypogonadism (with replacement therapy). African-American women have a decreased risk, partly because they begin menopause with a higher bone mineral density and have a lower rates of bone loss after menopause. Of all these, age is also a predictor of fracture independent of bone mineral density.

Evidence supporting this recommendation is of classes: A, B, C, D, M, R

Refer to the original guideline document for information on relationship of bone mineral loss with body habitus; family history of osteoporosis; cigarette smoking; sedentary lifestyle; alcohol, calcium, and vitamin D intake; and increased likelihood of falling.

6. Low Pre-Test Probability of Low BMD and Future Fracture

The following individuals are at low risk of low bone density and future fracture; bone density testing in general is not recommended:

1. Premenopausal women who have not had a fracture with minor trauma, are not on chronic glucocorticoid therapy, do not have secondary amenorrhea, and do not have a chronic disease associated with bone loss
2. Eugonadal men who have not had a fracture with minor trauma, are not on glucocorticoid therapy, and do not have another chronic disease associated with bone loss
3. Postmenopausal women under age 65 who have been on hormone replacement therapy since menopause and who do not have any significant additional risk factors.

Evidence supporting this recommendation is of classes: C, D, M, R

7. Address/Reinforce Options for Prevention of Osteoporosis

Osteoporosis is the consequence of continued bone loss throughout adulthood. Because of this, providers are encouraged to periodically review primary prevention strategies (see Annotation #4, "Discuss Primary Prevention of Fractures") and historical risk factors (see Annotation #5, "Discuss Risk Factors for Osteoporosis and Osteoporotic Fracture") with their

patients. Preventive health maintenance exams provide an excellent opportunity for this review.

8. High Pre-Test Probability of Low BMD and Future Fracture

Key Points:

- Patients can be risk-stratified to determine the appropriateness of bone density testing.

The following individuals are at sufficiently high risk for low bone mass and future fracture that a bone mineral density test is justified to further define that risk. This assumes that the individual being tested is willing to consider pharmacologic treatment for low bone mass documented on a bone density test. The first three of these indicate individuals at particularly high risk of bone loss and future fracture.

1. Prior fracture with minor trauma (fall from standing height or less)
2. Those who have been or are anticipated to be on glucocorticoid therapy for 3 or more months at a dose equivalent to or greater than 5.0 mg prednisone per day
3. Radiographic osteopenia or vertebral deformity consistent with fracture
4. All women 65 years of age or older
5. Postmenopausal women less than age 65 with one of the following additional risk factors
    a. Body weight less than 127 lbs or body mass index $\leq$20
    b. History of nontraumatic fracture after age 45 in a first-degree relative
    c. Current smoker
    d. Not using hormone replacement therapy
    e. Surgical menopause, or natural menopause before age 40
    f. On hormone therapy greater than 10 to 15 years
6. Chronic diseases known to be associated with bone loss (see Annotation Appendix A, "Secondary Causes of Osteoporosis" in the original guideline document)
7. Premenopausal women with amenorrhea greater than 1 year
8. Men with hypogonadism more than 5 years
9. Prolonged severe loss of mobility (unable to ambulate outside of one's dwelling without a wheelchair for greater than one year)
10. Solid organ or allogeneic bone marrow transplant recipient

Refer to the original guideline document for more information.

Evidence supporting this recommendation is of classes: C, D, M, R

9. Recommend Bone Density Assessment

Key Points:

- BMD measurement is the single best prediction of fracture risk as well as an objective way to monitor patient's response to treatment.

Measurements of BMD can predict fracture risk and allow for the identification of people who are at increased risk of fracture. Reviews of prospective cohort studies and case control studies have documented a direct relationship between decreasing BMD and increasing bone fracture risk. Additionally, there is strong evidence that increases in BMD with therapy for osteoporosis lead to substantial reductions in fracture incidence. Therefore, densitometry offers an objective measurement of a patient's response to treatment over time.

Current practice is to describe an individual's bone mineral density as compared to a reference normal population. In this sense, a T-score is the number of standard deviations above or below the mean for a young adult healthy population. A T-score is calculated from the following equation:

[(measured BMD - young adult population mean BMD) / young adult population SD]

A Z-score is the number of standard deviations above or below the mean for gender-, ethnicity-, and age-matched healthy population. A Z-score is calculated from the following equation:

[(measured BMD - age-matched population mean BMD) / age-matched population SD]

Normal, osteopenia, and osteoporosis are defined by the lowest of lumbar spine, femoral neck, track outer of total femur T-score, according to the World Health Organization (WHO). Although the following classifications were originally drafted for Caucasian postmenopausal women, some controversy exists as to whether the same diagnostic criteria can be applied to other groups.

- Normal: A T-score greater than or equal to -1
- Osteopenia: A T-score between -1 and -2.5
- Osteoporosis: A T-score less than or equal to -2.5
- The term "severe osteoporosis" is reserved for patients with both a fragility fracture(s) and a T-score less than or equal to -2.5.

For patients who decline bone density testing, reinforce osteoporosis prevention, consider gonadal hormone replacement therapy, and follow-up discussion of osteoporosis at future preventive visits.

Refer to the original guideline document for more information.

Evidence supporting this recommendation is of classes: C, M, R

10. Post-Test Probability

Key Points:

- BMD test results provide good information in predicting future fracture risk.

- Other historical factors that relate to bone quality augment BMD data in modifying risk.

Fracture risk in an individual patient is defined as the likelihood of sustaining an osteoporotic fracture over an interval of time. Current fracture risk is defined as the likelihood of an osteoporotic fracture in the patient's remaining lifetime years.

Current fracture risk can be expressed in terms of absolute risk, relative risk, or incidence (annual) risk. Absolute fracture risk is the actual risk of fracture for a given patient. Relative risk of fracture is the ratio of the absolute risk of fracture for the patient compared to the absolute risk of fracture for a young adult-, gender-, and ethnicity-matched reference population. Relative risk of fracture is increased by 1.5 to 3.0 times for each 1.0 standard deviation decrease in bone density below the mean for young adults of the same gender and ethnicity. Fracture risk data in elderly postmenopausal women suggest that fracture prediction is nearly equal regardless of the skeletal site assessed or the type of technology used, with the exception that hip fracture risk is best predicted by proximal femoral bone mineral density measurement. Similar data are being accumulated for men, although the numbers of studies published so far are much smaller. Prospective data allows prediction of 10-year fracture risk based on age and bone mineral density alone in post-menopausal women. This risk must be adjusted according to other clinical findings.

Evidence supporting this recommendation is of classes: B, C

11. Low Risk of Future Fracture

Low fracture risk is clinically defined by a bone mineral density T-score above -1.0 (normal bone density by the WHO definition).

12. Increased Risk of Future Fracture

Key Points:

- The T-score is best used in combination with other patient information to predict a given patient's fracture risk.

Even though osteoporosis is defined by a BMD T-score of less than -2.5, and osteopenia is defined as a T-score of -1 to -2.5, and the relative risk for fracture is directly correlated to T-score bone density, the absolute risk of fracture is not only related to bone density but also by bone quality and other non-bone density risk fractures for fracture.

Some patients with very low T-scores will never sustain an osteoporotic fracture, whereas some patients with normal T-scores will have fractures. Patients who fall infrequently are less likely to sustain osteoporotic fractures.

Previous osteoporotic fractures sustained by the patient, history of osteoporotic fractures sustained by the patient's family members, increased

rate of bone turnover, the patient's risk of falling, and the use of medications that predispose to falling, also help predict future fracture risk.

Some of these risk factors are modifiable, and some are not. However, none of these factors, singly or in combination, predict likelihood of future osteoporotic fracture as well as measurement of bone mineral density. About 80% of the variance in bone strength and resistance to fracture in animal models is explained by bone mineral density, and numerous studies have demonstrated that fracture risk is predicted by bone mineral density.

Patients found to have low risk of future fracture by bone mineral density testing should not automatically be assumed to remain at low risk of future fracture over their remaining lifetime years. Patients should be periodically reassessed by reviewing risk factors for osteoporosis, evaluating current primary prevention efforts, reviewing the clinical history for osteoporotic fractures subsequent to the initial bone density evaluation, and measuring bone mineral density. Clinical judgment must be used in determining the appropriate intervals between repeated measurements of bone mineral density over time. In some patients, such as those expected to have high bone turnover and rapid bone loss due to early postmenopausal status, initiation or continuation of steroid therapy, organ transplantation, or other causes, it may be appropriate to remeasure bone density as soon as 6-12 months after the initial measurement. In those patients not expected to have high turnover or rapid loss, it is appropriate to remeasure bone density at an appropriate interval, such as two to five years after the initial measurement, in order to detect patients who lose significant bone density over time.

13. Consider Secondary Causes and Further Diagnostic Testing

Key Points:

- A minimum screening laboratory profile should be considered in all patients with osteoporosis.

At this time there is no consensus about the routine use of serum and/or urine markers of bone turnover in the evaluation of patients with osteoporosis. See the ICSI Technology Assessment Report #53, Biochemical Markers for Bone Turnover in Osteoporosis, for more information.

Certain diseases are commonly associated with bone loss. These diseases are listed in Annotation Appendix A, "Secondary Causes of Osteoporosis," in the original guideline document. In broad categories, these include chronic inflammatory autoimmune conditions, endocrinopathies, malignancies, and malabsorptive states.

Consider the following evaluation for the patient with osteoporosis without prior workup:

- A biochemical profile that provides information on:
    - Renal function
    - Hepatic function

        - Calcium (important if starting an antiresorptive or anabolic agent)
            - elevated in hyperparathyroidism
            - decreased in malabsorption, vitamin D deficiency
        - Alkaline phosphatase
            - elevated in Paget's Disease, prolonged immobilization, acute fractures and other bone diseases
        - Phosphorus
            - decreased in osteomalacia
    - A complete blood count may suggest bone marrow malignancy or infiltrative process (anemia, low white blood cell count [WBC], or low platelets) or malabsorption (anemia, microcytosis, or macrocytosis).
    - An elevated sedimentation rate or C-reactive protein may indicate an inflammatory process or monoclonal gammopathy.
    - Thyroid-stimulating hormone (TSH) and thyroxine
    - The 24-hour urinary calcium excretion on a high-calcium intake screens for malabsorption and hypercalciuria, a correctable cause of bone loss. Low 24-hour urine calcium suggests vitamin D deficiency, osteomalacia, or malabsorption due to small bowel diseases such as celiac sprue.
    - Intact parathyroid hormone
    - 25-OH vitamin D

    Consider adding the following tests if clinically indicated: Osteoporosis and an age-matched bone density that is greater than one standard deviation below age-matched controls (Z-score <-1.0): In this population it is important to screen for treatable secondary causes of bone loss that may not be clinically evident in patients with a lower than expected bone density or premature osteoporotic fracture. (See Annotation Appendix A, "Secondary Causes of Osteoporosis" in the original guideline document for a comprehensive list of secondary causes of osteoporosis).

    - Testosterone (total and free) in men and estradiol in women; luteinizing hormone (LH) and follicle-stimulating hormone (FSH) and prolactin if evidence of hypogonadotropic hypogonadism
    - Tissue transglutaminase if clinical suspicion for gluten enteropathy
    - 24-hour urinary free cortisol or overnight dexamethasone suppression test if clinical suspicion of glucocorticoid excess
    - Serum and urine protein electrophoresis, with a conditional immunoelectrophoresis

    Refer to Annotation Appendix A, "Secondary Causes of Osteoporosis" in the original guideline document for a table with the common causes of secondary osteoporosis.

    Evidence supporting this recommendation is of classes: D, R

14. Address Options for Prevention and Treatment of Osteoporosis

    Key Points:

- Lifestyle adjustments are traditionally first-line therapy for osteoporosis prevention.
- Bisphosphonates have the strongest data showing risk reductions in both vertebral and non-vertebral fractures.
- Estrogen is considered first-line therapy for the prevention of osteoporosis in prematurely menopausal women under the age of 50.
- Anabolic therapy is indicated for patients with particularly high-risk for future fracture.
- Nasal calcitonin is not considered a first-line treatment for osteoporosis, but may be useful in some populations.

Please see the medication tables in Annotation Appendix B of the original guideline document, "Recommended Pharmacologic Agents" for specific information on pharmacologic agents for treatment and prevention of osteoporosis.

Osteoporosis Prevention

Estrogen has traditionally been considered first-line therapy for prevention of osteoporosis in prematurely menopausal women under the age of 50. If the only reason hormone therapy has been prescribed is for osteoporosis prevention, other therapies should be considered. If the decision is made to discontinue estrogen, a BMD should be obtained to determine if other bone loss prevention therapies are needed. Other medications for prevention include bisphosphonates and raloxifene.

Osteoporosis Treatment

Bisphosphonates have the strongest data showing risk reductions in both vertebral, hip, and other nonvertebral fractures. Other treatments include raloxifene (see SERM in this annotation) and calcitonin.

Parathyroid hormone 1-34 (teriparatide) (PTH) is used for patients at highest risk for fracture. It could be first-line therapy for those patients.

Post-transplantation Bone Loss

Antiresorptive therapy may be effective at preventing bone density loss after transplantation. Considering the rates of bone loss after transplantation described in Annotation #3, bone mineral density testing should be performed every 6 months to one year until bone mineral density is shown to be stable or improving on therapies for osteoporosis. Studies demonstrate that standard calcium and vitamin D supplementation, with or without calcitonin, are not able to prevent bone loss after transplantation. Other studies indicate that pharmacologic vitamin D preparations or intravenous bisphosphonates, such as pamidronate, or zoledronic acid, or oral bisphosphonates, such as alendronate or risedronate are more likely to prevent bone loss after transplantation.

Alternative and Complementary Agents for Prevention and Treatment of Osteoporosis

There is conflicting data on a number of non-Food and Drug Administration (FDA) approved substances for possible use in prevention and treatment of osteoporosis. These include phytoestrogens, synthetic isoflavones such as ipriflavone, natural progesterone cream, magnesium, vitamin K and eicosapentaenoic acid. There is very limited data from randomized controlled trials of these agents for prevention or treatment of osteoporosis. A recently reported, multicenter randomized trial of ipriflavone showed no significant effect on bone density or risk of vertebral fractures.

Evidence supporting this recommendation is of classes: A, B, C, D, M, R

In addition to calcium, vitamin D, physical therapy, surgical repair, and radiologic intervention as appropriate, the therapies listed below may be used. Clinicians should be aware that patient compliance with adherence to osteoporosis therapy has been historically poor.

Gonadal Hormone Therapy

Female Gonadal Hormone Therapy

The use of supplemental estrogen in the immediate postmenopause has been well accepted in preventing the rapid loss of bone that occurs in this interval.

Supplemental estrogen not only retards accelerated bone loss, but has also been shown to create a gain in bone density. In the PEPI trial after 3 years, the women receiving hormone replacement therapy had a mean 5% gain in bone density in the spine and 2% in the hip compared to a 2% loss in the placebo group. Preliminary evidence suggests that the gain in bone mass may persist beyond the first few years. In one study, women on estrogen-progestin therapy showed a persistent increase in density over 10 years, reaching 13% over baseline.

It is generally believed that estrogen therapy is most effective when started immediately after menopause. But estrogen therapy has also been shown to have a positive effect on bone mass long after menopause, creating gains of bone mass of 5 to 10% over baseline over 1 to 3 years.

The protective effects of estrogen on bone density are lost quickly after estrogen is discontinued.

Dose response effectiveness of hormone therapy on bone mass has recently undergone considerable scrutiny.

Ultra-low estrogen supplementation has been shown to be effective in severely hypoestrogenic women in improving bone mass. Fracture data is pending.

Refer to the original guideline document for more information on female gonadal hormone therapy.

Male Gonadal Hormone Therapy

The bone loss associated with male hypogonadism is reversed by testosterone therapy at least partly via aromatization to estrogen. Testosterone therapy, although not FDA-approved for osteoporosis, seems a reasonable first therapeutic intervention in men symptomatic with hypogonadism who do not have contraindications to the use of testosterone therapy.

Bisphosphonates

Treatment and Prevention of Osteoporosis in Postmenopausal Women

Alendronate has been shown to increase bone mineral density and reduce the incidence of vertebral, hip, and non-vertebral fractures in postmenopausal women having existing vertebral fractures, and those with low bone mineral density (approximately 2.1 SD below peak) compared to placebo (calcium and vitamin D).

Excellent clinical trial data supports the use of oral bisphosphonates for preventing fractures in patients diagnosed with postmenopausal osteopenia or osteoporosis. The best clinical trials have been done with alendronate (Fosamax®) and risedronate (Actonel®). [Conclusion Grade I: See Conclusion Grading Worksheet -- Appendix B of the original guideline document, -- Annotation #14 (Bisphosphonates for Primary Osteoporosis)]. Ibandronate (Boniva®) has been added to the list of effective bisphosphonates. (See Appendix B, "Recommended Pharmacologic Agents" in the original guideline document.)

Treatment of Osteoporosis in Men

Alendronate has been shown to increase bone mineral density at the spine, hip, and total body and prevents vertebral fractures and decreases in height for men with osteoporosis.

Good clinical trial data support the use of alendronate for preventing bone loss in men diagnosed with osteoporosis. [Conclusion Grade I: See Conclusion Grading Worksheet -- Appendix B of the original guideline document, -- Annotation #14 (Bisphosphonates for Primary Osteoporosis)].

Treatment and Prevention of Glucocorticoid-Induced Osteoporosis

Alendronate increases lumbar spine, femoral neck, trochanter, and total body bone mineral density in patients who require long-term (at least one year) glucocorticoid therapy at dosages of at least 7.5 mg daily.

Risedronate has also been shown to increase bone mineral density in patients receiving glucocorticoid therapy. Treatment with risedronate 5 mg a day did have a trend of reduced fracture incidence.

Clinical trial data supports the use of oral bisphosphonates for reducing bone loss in men and women diagnosed with glucocorticoid-induced bone loss. The

best clinical trials have been done with alendronate (Fosamax®) and risedronate (Actonel®). [Conclusion Grade II: See Conclusion Grading Worksheet -- Appendix C in the original guideline document, -- Annotation # 14 (Bisphosphonates for Glucocorticoid-induced Bone Loss)].

Clinical trial data suggests that oral bisphosphonates may reduce fracture risk in men and women diagnosed with glucocorticoid-induced bone loss. [Conclusion Grade III: See Conclusion Grading Worksheet -- Appendix C of the original guideline, -- Annotation #14 (Bisphosphonates for Glucocorticoid-induced Bone Loss)].

Post-transplantation

Solid organ transplantation of all types and allogeneic bone marrow transplantation are associated with rapid bone loss after transplantation. In addition, many patients develop significant bone loss before transplantation.

Several small studies have shown that intravenous pamidronate may prevent bone loss after organ transplantation. A few small studies have evaluated oral bisphosphonate therapy in post-transplant patients.

Selective Estrogen Receptor Modulator (SERM)

The only SERM approved for the prevention and treatment of osteoporosis is raloxifene.

Prevention and Treatment of Osteoporosis in Postmenopausal Women

The MORE trial was a large 3-year randomized placebo-controlled study in postmenopausal women with osteoporosis. Raloxifene showed an increase in BMD and reduced the risk of vertebral fractures. The risk of non-vertebral fractures did not differ between placebo and raloxifene. There was an increased risk of venous thromboembolism compared with placebo.

Calcitonin

Treatment of Osteoporosis in Postmenopausal Women

Nasal-calcitonin 200 IU daily has shown a 33% risk reduction in new vertebral fractures compared with placebo (RR 0.67, 95% CI 0.47-0.97, p = 0.03). This occurred without significant effects on BMD. BMD measurements were not blinded to investigators and 59% (744) participants withdrew from the study early. Also, a dose response was not observed with respect to risk reduction of vertebral fractures.

Post-transplantation

Several studies have shown that nasal spray calcitonin has little effect on prevention of bone loss after organ or bone marrow transplantation.

Refer to the original guideline document for information on anabolic agents, strontium, combination therapy (estrogen and bisphosphonates); comparative trials; calcitriol-1 25-OH vitamin D; and alternative and complimentary agents (phytoestrogens, ipriflavone, natural progesterone, magnesium, vitamin K, eicosapentaenoic, and gamma-linolenic acid supplementation, and campo formulae).

15. Follow-Up Testing After Pharmacologic Intervention

Key Points:

- Periodic follow-up central DXA's on the same machine is recommended for following patients on pharmacologic therapy.
- The testing interval varies from 6 to 24 months depending on the clinical situations.

Sequential bone density testing using central DXA may be useful, and is generally recommended in monitoring drug therapy for the treatment of osteopenia or osteoporosis. Ideally, such testing should be performed at 12 to 24 months on the same machine as the pre-treatment bone density. A frequency as often as every 6 to 12 months may be indicated in the case of glucocorticoid treated patients or those on suppressive doses of thyroid hormone. Other patients at risk for accelerated bone loss include women at early menopause or those who have discontinued estrogen and are not on another bone protective agent*. The lumbar spine and the total proximal femur have the highest reproducibility and are the preferred sites for monitoring therapy. Changes in BMD should only be reported as significant if they exceed the "least significant change" for the DXA center. Stability or increase in BMD indicates successful therapy. A significant decline in BMD may require further investigation.

A significant decrease in BMD on therapy may be due to:

- Poor drug adherence
- Improper medication administration technique in the case of bisphosphonates
- A missed secondary cause of osteoporosis (e.g., hyperparathyroidism, malabsorption)
- Inadequate calcium intake
- Untreated Vitamin D deficiency
- A true treatment failure due to the drug itself

The role of further follow-up BMDs after stability or improvement over 3 to 4 years has been demonstrated and is recommended by most experts. No study has been done as to whether follow-up BMDs on therapy enhance fracture risk reduction but they may affect patient adherence to therapy. Therapy should not be withheld if follow-up bone density testing is not available.

*Medicare provides coverage for bone densitometry with central DXA every two years to monitor osteoporosis therapy.

Definitions:

Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results of different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

Classes of Research Reports:

A. Primary Reports of New Data Collection:

Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Non-randomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series

- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M:

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

CLINICAL ALGORITHM(S)

A detailed and annotated clinical algorithm is provided for Diagnosis and Treatment of Osteoporosis.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The guideline contains an annotated bibliography and discussion of the evidence supporting each recommendation. The type of supporting evidence is classified for selected recommendations (see "Major Recommendations").

In addition, key conclusions contained in the Work Group's algorithm are supported by a grading worksheet that summarizes the important studies pertaining to the conclusion. The type and quality of the evidence supporting these key recommendations (i.e., choice among alternative therapeutic approaches) is graded for each study.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Overall Benefits

- Appropriate recognition, prevention, and treatment of osteoporosis and subsequent decrease in bone loss and fracture risk and increase in bone health
- Improved diagnostic and therapeutic follow-up of adults presenting with a history of low-impact fracture

- Increased evaluation for osteoporosis risk factors in all adults presenting for a preventive visit and stratification into appropriate risk group

POTENTIAL HARMS

Side Effects of Medication

- Raloxifene. Worsening hot flashes and leg cramps, and increased risk of thromboembolic events are reported side effects of raloxifene.
- Bisphosphonates. Oral bisphosphonate preparations have the potential to cause upper gastrointestinal erosions and ulcerations on rare occasions.
- Calcitonin. Nausea, flushing, rhinitis with nasal spray
- Estrogen. Bloating, breast tenderness, uterine bleeding, increased risk of thromboembolic events, increased cardiac events, and breast cancer

See Appendix B of the original guideline document for a more complete list of adverse drug reactions.

CONTRAINDICATIONS

CONTRAINDICATIONS

- Alendronate (Fosamax). Contraindications include abnormalities of the esophagus which delay esophageal emptying, inability to stand or sit upright for at least 30 minutes, hypersensitivity, and hypocalcemia. It is not recommended for patients with creatinine clearance (CrCl) equal to or less than 35 mL/min.
- Risedronate (Actonel). Contraindications include inability to stand or sit upright for at least 30 minutes, hypersensitivity, and hypocalcemia. It is not recommended for patients with CrCl equal to or less than 30 mL/min.
- Ibandronate (Boniva). Contraindications include hypocalcemia, inability to stand or sit upright for at least 60 minutes, and hypersensitivity. It is not recommended for patients with CrCl equal to or less than 30 mL/min.
- Raloxifene (Evista). Contraindications include pregnancy, history of thromboembolism, and hypersensitivity.
- Teriparatide (Forteo). Contraindications include Paget's disease, children, prior radiation therapy involving the skeleton, bone metastases or history of skeletal malignancies, metabolic bone disease (other than osteoporosis), hypercalcemia, pregnant and nursing women, and unexplained elevated alkaline phosphatase.
- Calcitonin-salmon (Miacalcin nasal spray). Contraindications include hypersensitivity.
- Estrogens. Contraindications include pregnancy, history of thromboembolic disorders, breast cancer, estrogen dependent neoplasia, undiagnosed abnormal vaginal bleeding, and hypersensitivity.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These clinical guidelines are designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and are not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. A guideline will rarely establish the only approach to a problem.
- This medical guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients are urged to consult a health care professional regarding their own situation and any specific medical questions they may have.
- There is very limited data from randomized controlled trials of alternative and complementary agents for prevention or treatment of osteoporosis.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Once a guideline is approved for general implementation, a medical group can choose to concentrate on the implementation of that guideline. When four or more groups choose the same guideline to implement and they wish to collaborate with others, they may form an action group.

In the action group, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently, action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment, and tobacco cessation.

The following detailed measurement strategies are presented to help close the gap between clinical practice and the guideline recommendations.

Priority Aims and Suggested Measures of Health Care Systems

1. Improve diagnostic and therapeutic follow-up of adults presenting with a history of low-impact fracture.

   Possible measures of accomplishing this aim:

   a. Percentage of adults presenting with a history of low-impact fracture who have had bone densitometry
   b. Percentage of postmenopausal women and men with a history of low-impact fracture evaluated and offered treatment for osteoporosis
   c. Percentage of adults with a history of low-impact fracture offered treatment for osteoporosis
   d. Percentage of adults with a history of low-impact fracture with documentation of discussion with a health care provider of osteoporosis risk offered treatment for osteoporosis

2. Increase the evaluation for osteoporosis risk factors in all adults presenting for a preventive visit.

   Possible measures for accomplishing this aim:

   a. Percentage of patients presenting for a preventive visit with documentation of assessment of risk factors for osteoporosis
   b. Percentage of patients at risk for fracture who have had bone densitometry

Note: At this point in development for this guideline, there are no specifications written for possible measures listed above. Institute for Clinical Systems Improvement (ICSI) will seek input from the medical groups on what measures are of most use as they implement the guideline. In a future revision of the guideline, one or two measurement specifications may be included.

IMPLEMENTATION TOOLS

Clinical Algorithm
Patient Resources
Pocket Guide/Reference Cards

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Diagnosis and treatment of osteoporosis. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2005 Sep. 61 p. [162 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2002 Aug (revised 2005 Sep)

GUIDELINE DEVELOPER(S)

Institute for Clinical Systems Improvement - Private Nonprofit Organization

GUIDELINE DEVELOPER COMMENT

Organizations participating in the Institute for Clinical Systems Improvement (ICSI): Affiliated Organizations participating in the Institute for Clinical Systems Improvement (ICSI): Affiliated Community Medical Centers, Allina Medical Clinic, Altru Health System, Aspen Medical Group, Avera Health, CentraCare, Columbia Park Medical Group, Community-University Health Care Center, Dakota Clinic, ENT Specialty Care, Fairview Health Services, Family HealthServices Minnesota, Family Practice Medical Center, Gateway Family Health Clinic, Gillette Children's Specialty Healthcare, Grand Itasca Clinic and Hospital, HealthEast Care System, HealthPartners Central Minnesota Clinics, HealthPartners Medical Group and Clinics, Hutchinson Area Health Care, Hutchinson Medical Center, Lakeview Clinic, Mayo Clinic, Mercy Hospital and Health Care Center, MeritCare, Mille Lacs Health System, Minnesota Gastroenterology, Montevideo Clinic, North Clinic, North Memorial Care System, North Suburban Family Physicians, Northwest Family Physicians, Olmsted Medical Center, Park Nicollet Health Services, Pilot City Health Center, Quello Clinic, Ridgeview Medical Center, River Falls Medical Clinic, Saint Mary's/Duluth Clinic Health System, St. Paul Heart Clinic, Sioux Valley Hospitals and Health System, Southside Community Health Services, Stillwater Medical Group, SuperiorHealth Medical Group, University of Minnesota Physicians, Winona Clinic, Ltd., Winona Health

ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; e-mail: icsi.info@icsi.org; Web site: www.icsi.org.

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GUIDELINE COMMITTEE

Committee on Evidence-Based Practice

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Work Group Members: Christine Simonelli, MD (Work Group Leader) (HealthEast Clinics) (Internal Medicine); Bart Clarke, MD (Mayo Clinic) (Endocrinology); Daniel Cohan, DO (North Clinic) (Family Practice); Richard Kopher, MD (HealthPartners Medical Group) (Gynecology); Dana Battles, MD (Aspen Medical Group) (Internal Medicine); Robert Florence, MD (Aspen Medical Group) (Internal Medicine); Philip Hoversten, MD (Allina Medical Clinic) (Internal Medicine); John Schousboe, MD

(Park Nicollet Health Services) (Rheumatology); Vy Vy Vo, PharmD (HealthPartners Medical Group) (Pharmacy); Renee Compo, RN, CNP (HealthPartners Medical Group) (Nursing); Sharon Verville, Tech (Sioux Valley Health System) (Nursing); Amy Murphy, MHHA (Institute for Clinical Systems Improvement) (Measurement/Implementation Advisor); Linda Setterlund, MA (Institute for Clinical Systems Improvement) (Facilitator)

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

In the interest of full disclosure, Institute for Clinical Systems Improvement (ICSI) has adopted a policy of revealing relationships work group members have with companies that sell products or services that are relevant to this guideline topic. The reader should not assume that these financial interests will have an adverse impact on the content of the guideline, but they are noted here to fully inform readers. Readers of the guideline may assume that only work group members listed below have potential conflict of interest to disclose.

John Schousboe, MD receives grant support from Merck, and Procter & Gamble.

Christine Simonelli, MD receives grant support from Merck, Novartis, Eli Lilly, and Procter & Gamble, serves as a consultant for Procter & Gamble and Merck, and is a member of the Speaker's Bureau for Amgen.

Bart Clarke, MD, receives grant support and serves as a consultant for Merck and is a member of the Speaker's Bureau for Amgen.

Robert Florence receives speaker's fees from Eli Lilly and Proctor & Gamble

No other work group members have potential conflicts of interest to disclose.

ICSI's conflict of interest policy and procedures are available for review on ICSI's website at www.icsi.org.

GUIDELINE STATUS

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary.

GUIDELINE AVAILABILITY

Electronic copies of the updated guideline: Available from the Institute for Clinical Systems Improvement (ICSI) Web site.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Diagnosis and treatment of osteoporosis. Executive summary. Bloomington (MN): Institute for Clinical Systems Improvement, 2005 Sep. 1 p. Electronic copies: Available from the Institute for Clinical Systems Improvement (ICSI) Web site.
- ICSI pocket guidelines. May 2005 edition. Bloomington (MN): Institute for Clinical Systems Improvement, 2005. 362 p.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

PATIENT RESOURCES

The following is available:

- Diagnosis and treatment of osteoporosis. Bloomington (MN): Institute for Clinical Systems Improvement, 2005 Oct. 17 p.

Electronic copies: Available from the Institute for Clinical Systems Improvement (ICSI) Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This summary was completed by ECRI on December 24, 2002. The information was verified by the guideline developer on January 23, 2003. This summary was updated by ECRI on April 12, 2004, on September 16, 2004, and most recently on October 21, 2005.

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